UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,154	01/21/2004	Jun-Ichi Nezu	14875-057002 / C2-906DP1P	4898

26161 7590 04/13/2010

FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
BUNNER, BRIDGET E	

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
04/13/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JUN-ICHI NEZU and ASUKA OKU

Appeal 2009-010405
Application 10/762,154
Technology Center 1600

Decided: April 9, 2010

Before ERIC GRIMES, JEFFREY N. FREDMAN, and STEPHEN WALSH, *Administrative Patent Judges*.

WALSH, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134(a) involving claims to an isolated nucleic acid, a vector, a host cell and a method of producing a polypeptide. The Patent Examiner rejected the claims for lack of utility and enablement. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

The invention is said to relate to transporters, i.e., "proteins involved in transport of substances from the outside to the inside of cells or vice versa." (Spec. 1:9-11.) The Specification states that "[t]he inventors discovered an unknown gene showing a significant homology with those for organic cation transporters, OCT1 and OCT2." (*Id.* at 4:27-29.) The Specification is said to disclose "novel transporter genes, proteins encoded by these genes, and their use" (*id.* at 5:9-10), and it designates certain novel transporters as "human OCTN1," "human OCTN2," (*id.* at 6:6-9), "mouse OCTN1" and "mouse OCTN2" (*id.* at 6:24-28).

Claims 8, 10, 11, 13, 16, 18-21, 23-25, 27, 32 and 36 are on appeal.[1] Claim 8 is representative and reads as follows:

8. An isolated nucleic acid encoding a polypeptide comprising the sequence of SEQ ID NO:1.

The Examiner rejected the claims under 35 U.S.C. § 101 "because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility" (Ans. 3). The Examiner also rejected the claims under 35 U.S.C. § 112, first paragraph, concluding that "[because] the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility . . . one skilled in the art clearly would not know how to use the claimed invention" (*id.* at 7).

---

[1] Claims 1-7, 9, 12, 14, 15, 17, 22, 26 and 28-31 were canceled, and claims 33-35 were withdrawn. (App. Br. 1.)

UTILITY

The Issue

The Examiner's position is that the Specification does not teach "any physiological significance or functional characteristics of the OCTN1 polynucleotide . . . or polypeptide." (Ans. 4.) "Without any information as to the specific properties of OCTN1, the mere identification of the polypeptide is not sufficient to impart any particular utility to the claimed polynucleotides." (*Id.* at 5.)

Appellants contend that the Specification disclosed using OCTN1 in screens for carcinostatic compounds transported by the protein. (App. Br. 5.) According to Appellants, "carcinostatic compounds that are identified in a screen with hOCTN1 transporter protein have the specific and substantial use of being carcinostatic compounds." (*Id.*) Appellants further point out that examples in the Specification demonstrated that the screening works. (*Id.* at 9.)

The issue with respect to this rejection is whether the evidence supports finding that screening for carcinostatic compounds that can be transported by OCTN1 is not a specific and substantial utility.

Findings of Fact

1. The Specification states that the results of testing described in the Specification "revealed that human OCTN1 has the activity to transport actinomycin D, etoposide, vinblastine, and daunomycin," which are said to have been used as carcinostatics. (Spec. 31:5-12.)
2. The Specification states that "[b]y designing and screening drugs utilizing the substrate specificity of OCTN1 so as to be readily

> recognized by this transporter, it would be possible to efficiently develop useful drugs that can be readily absorbed by the cells." (*Id.* at 31:12-16.)

Principles of Law

> [A]n application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the "substantial" utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public. . . . in addition to providing a "substantial" utility, an asserted use must also show that the claimed invention can be used to provide a well-defined and particular benefit to the public.

In re Fisher, 421 F.3d 1365, 1371 (Fed. Cir. 2005).

"It is well established that the enablement requirement of § 112 incorporates the utility requirement of § 101." *Fisher*, 421 F. 3d at 1378.

Analysis

The evidence contradicts the Examiner's finding that the Specification merely identified OCTN1, without disclosing a biological function. Instead, the Specification demonstrated that OCTN1 works as a transport protein for carcinostatic drugs. (FF1.)

The Specification stated that OCTN1's substrate specificity could be exploited to develop useful drugs that can be readily absorbed by cells. (FF2.) The Examiner found this utility was not specific or substantial because "[s]uch assays can be performed with any polypeptide and nucleic acid." (Ans. 6.) There is no evidence that any random polypeptide can be

used in the specific assays that OCTN1 can be used for, and we agree with Appellants that the Examiner is simply wrong on that point. *See* App. Br. at 7. There is also no evidence that those in this art regard transporter screening assays as insubstantial uses, lacking in practical application. The scientific literature that Appellants cite supports the opposite proposition. *See* App. Br. at 11.

For the reasons given in Appellants' Brief, we agree that the evidence does not support the utility rejection. As the enablement rejection relied only on the utility rejection, we reverse it as well.

CONCLUSION

The evidence of record does not support finding that screening for carcinostatic compounds that can be transported by OCTN1 is not a specific and substantial utility.

SUMMARY

We reverse the rejection of Claims 8, 10, 11, 13, 16, 18-21, 23-25, 27, 32 and 36 under 35 U.S.C. § 101 for lack of utility; and we reverse the rejection of the same claims under 35 U.S.C. § 112, first paragraph, for lack of enablement.

REVERSED

clj

FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022